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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,588	04/17/2000	LARRY S. MILLSTEIN	LAMILL2	2048

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[REDACTED] EXAMINER

PRASTHOFER, THOMAS W

ART UNIT	PAPER NUMBER
1627	7

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary <i>file copy</i>	Application No.	Applicant(s)
	09/529,588	MILLSTEIN, LARRY S.
	Examiner Thomas W Prasthofer	Art Unit 1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 September 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 48-93 is/are pending in the application.
- 4a) Of the above claim(s) 80-93 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 48-79 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Status of the Application

Receipt is acknowledged of response to a restriction requirement on 06 September 2001 (Paper No. 8).

Status of the Claims

Claims 48-93 were pending in the present application. Claims 80-93 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 48-79 are pending in the present application and examined on their merits.

Response to Restriction and Election of Species with Traverse

Applicant's election with traverse of claims 48-79 (Group I) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that there would be no serious search burden for the PTO to search both Groups I and II. This is not found persuasive because applicant has not provided any reasons for the assertion that there would be no serious search burden to answer examiners reasons for a serious search burden.

The requirement is still deemed proper and is therefore made FINAL.

Objections to the Claims

1. Claim 76 is objected to because it lacks a period at the end of the sentence.

Claims Rejections – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (New Matter).

New claim 48 recites the limitation that array members “*are homogeneous compositions*.” This limitation does not appear to be supported by the specification and claims as originally filed. In accordance with MPEP 714.02, applicant should specifically point out where support for any amendments made to the disclosure can be found in the specification as originally filed.

3. Claims 48-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The presently claimed method requires structural elements as recited in the claims. The specification, however, is not enabling for the making of the structural elements recited. Consequently, using the presently claimed method would require undue experimentation on the part of one wishing to use it.

Several factors are to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any required experimentation is “undue.” These factors include:

- 1) the breadth of the claims
- 2) the nature of the invention

- 3) the state of the prior art
- 4) the level of one of ordinary skill
- 5) the level of predictability in the art
- 6) the amount of direction provided by the inventor
- 7) the existence of working examples
- 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims encompass any structural members whatsoever made from any material including any glass, plastic, ceramic, or metal. The cross sectional areas of the structural members encompass a range 1 micrometer to 1,000,000 micrometers. The array members may be absolutely any substance from atoms to molecules, mixtures of molecules, and other compositions so long as they are homogeneous. The materials of the structural members and array members must be compatible with cutting methods to provide wafers in thickness ranging from 2.5-2,500 micrometers. Applicant provides no guidance with respect to the manufacture of any of the structural members to the specifications required to use the claimed method. Nor has any guidance been provided for the compatibility of structural members and array members with each other or with the means used to cut sections of the claimed thickness. It is unpredictable whether a particular combination of structural material, array members, and means of sectioning is compatible or will allow the production of the claimed wafers. Applicant has provided no working examples. Substantial experimentation would be required of one of ordinary skill in the art to develop a means of manufacturing structural members according to the specifications required to use the claimed method, to develop a means of bundling the structural members, and aligning them in such a way to produce wafers that are replicate arrays.

Claims Rejections – 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 48-50, 52, 55, 57, 64-66, 73, 77, and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: method steps that provide a bundle of aligned members that can be sectioned to make replicate arrays. The method steps must include structural members, each with a lumen because the method recites compositions disposed within lumen.

B. Claim 48 recites the limitation "*disposed within lumen of structural members*" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim. The claim does not recite structural members that have lumen.

C. In claim 49, the term "alignment members" is not clear because one of ordinary skill in the art would not know the metes and bounds of what is encompassed by the term. The term is not defined by composition, structure, or function in such a way as to allow one to interpret the meaning of the term.

D. In claim 50, the term "embedded information" is not defined in the specification in such a way that one of ordinary skill in the art could ascertain the metes and bounds of the claim. One would not know what types of "information" are to be "embedded" or what it means for the information to be "embedded." For example, would a serial number from the manufacturer or the chemical composition of a portion of the "wafer" be considered "information?" Can the contents of the lumen be "embedded information?" Clarification is requested.

E. Claim 52 recites the limitation "*the first and second major surfaces*" in line 2. There is insufficient antecedent basis for this limitation in the claim.

F. The term "smooth" in claims 55 and 57 is a relative term which renders the claim indefinite. The term "smooth" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

G. In claim 57, it is not clear if the method of cross-sectioning is the only way of increasing the surface area of array members exposed encompassed by the claim. Clarification is requested.

H. In claims 64-66, it is not clear how the cross sectional area is to be determined because cross-sectioning can be performed by planar or nonplanar cross-sectioning. Clarification is requested.

I. In claim 73, it is not clear what the structure or metes and bounds of the term "*peptide-nucleic acids*" are.

J. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 77 recites the broad recitation nucleic acid, and the claim also recites DNA, RNA, ribozyme, oligonucleotide, and polynucleotides, which are narrower statements of the range/limitation. Claim 77 also recites the broad recitation protein, and the claim also recites glycoprotein, antibody, antibody-derived polypeptide, receptor protein, fusion protein, and lectin, which are narrower statements of the range/limitation. Other such combinations are also present in the claim (for example, an antigen may be almost any type of molecule).

K. Claim 79 depends from claim 71 and recites a limitation of "binding to the analyte." Claim 71, however, has no method step involving a binding step. Clarification is requested.

Claims Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 48-50, 52, 55, 58, 59, and 63-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Cathey et al. U.S. Patent No. 6,183,329 B1 September 2001.

The Cathey et al reference discloses a process for forming spacers in large area displays comprising the steps of forming bundles of fiber strands held together with a binder, and slicing the bundles into slices (i.e. wafers) (abstract). Column 7, lines 39-62 disclose that the fibers may be made of two types of glass, one serving as a core (i.e. array member) and the other as an enveloping glass tubing (i.e. structural member). The diameters of the glass fibers may be adjusted to, for example, 0.001 inches. Column 9, lines 45-53 disclose that the discs may be cut to a thickness of from 0.008 inches to 0.013 inches. Column 11, lines 27-58 discloses that black fibers (i.e. alignment members and/or information embedded in the wafer) may be included to serve as reference points for alignment of slices.

Consequently present claims 48-50, 52, 55, 58, 59, and 63-67 are anticipated by the Cathey et al reference.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas Prasthofer** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Thomas Prasthofer, Ph.D.

November 17, 2001



J-Venkat
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